

# VYTORIN®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using VYTORIN?

VYTORIN contains the active ingredient ezetimibe and simvastatin. VYTORIN is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

For more information, see Section [1. Why am I using VYTORIN?](#) in the full CMI.

### 2. What should I know before I use VYTORIN?

Do not use if you have ever had an allergic reaction to VYTORIN or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use VYTORIN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with VYTORIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use VYTORIN?

- The recommended dose is one VYTORIN 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening.
- For the best effect take VYTORIN at about the same time each day.

More instructions can be found in Section [4. How do I use VYTORIN?](#) in the full CMI.

### 5. What should I know while using VYTORIN?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using VYTORIN.

	<ul style="list-style-type: none"> <li>• If you become pregnant while taking VYTORIN, tell your doctor.</li> <li>• Have any blood tests your doctor requests to make sure VYTORIN is right for you.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not give VYTORIN to anyone else, even if they have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how VYTORIN affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Drinking large quantities of alcohol while taking VYTORIN may increase your chance of getting liver problems.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep VYTORIN in a cool dry place where the temperature stays below 30°C</li> </ul>

For more information, see Section [5. What should I know while using VYTORIN?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects of VYTORIN are diarrhoea and muscle pain.

Allergic reactions to ezetimibe, simvastatin or other ingredients of VYTORIN occur very rarely.

Serious side effects are rare, but may need urgent medical attention. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# VYTORIN®

**Active ingredient(s):** *ezetimibe and simvastatin*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using VYTORIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VYTORIN.**

**Where to find information in this leaflet:**

- [1. Why am I using VYTORIN?](#)
- [2. What should I know before I use VYTORIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VYTORIN?](#)
- [5. What should I know while using VYTORIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using VYTORIN?

**VYTORIN contains the active ingredients ezetimibe and simvastatin.** VYTORIN helps to lower cholesterol and triglyceride levels.

**VYTORIN is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately..**

## **Cholesterol**

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called 'good' cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

## **Triglycerides**

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

## **How VYTORIN works**

VYTORIN reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

VYTORIN works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver. VYTORIN does not help you lose weight.

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), VYTORIN reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Your doctor may have prescribed VYTORIN for another reason. Ask your doctor if you have any questions about why VYTORIN has been prescribed for you.

VYTORIN is not addictive.

## **2. What should I know before I use VYTORIN?**

### **Warnings**

#### **Do not use VYTORIN if:**

- you are allergic to ezetimibe, simvastatin, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breast feeding. VYTORIN is contraindicated (i.e. should not be used) during pregnancy and breastfeeding. If you take this medicine during pregnancy and breastfeeding, your baby may absorb this medicine and it may affect your baby's

normal development causing foetal malformations (birth defects) or irreversible damage.

- you have active liver disease or repeated blood tests indicating possible liver problems.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- You are taking certain medicines such as gemfibrozil, ciclosporin, danazol, fusidic acid and strong CYP3A4 inhibitors like itraconazole and ketoconazole. Please see 3. "What if I am taking other medicines" in this CMI for more information.
- the packaging is torn or shows signs of tampering.

### **Check with your doctor if you:**

- have kidney disease, diabetes or any other medical conditions
- have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Your doctor may do a blood test to check for certain muscle problems.
- are Asian.
- have, or have had, any medical conditions, including liver disease or liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.
- drink alcohol regularly.



- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.
- are taking niacin or a niacin-containing product.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. VYTORIN should not be used during pregnancy.

If you become pregnant while taking VYTORIN, stop taking it and tell your doctor immediately.

Talk to your doctor if you are breastfeeding or intend to breastfeed. VYTORIN should not be used while breast feeding.

## **Use in Children and Adolescents**

- VYTORIN is used in children and adolescents (10 to 17 years of age) to treat familial

hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e. passed on through families).

- VYTORIN is not recommended for use in children under 10 years of age, as there have been no studies of its effects in this age group.
- Your doctor will assess whether VYTORIN is suitable for your child. Depending on the pubertal development of your child, VYTORIN may not be suitable for him or her.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines should not be taken with VYTORIN. If you are taking any of them, your doctor may suggest stopping VYTORIN temporarily or permanently. These include:**

- nefazodone, used to treat depression
- medicines containing cobicistat, a drug used in the treatment of HIV infection.
- protease inhibitors, including indinavir, nelfinavir, ritonavir, saquinavir, used to treat HIV infection
- certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- gemfibrozil, used to treat high cholesterol levels
- ciclosporin, used to suppress the immune system
- danazol

- erythromycin, clarithromycin, telithromycin and fusidic acid, antibiotics used to treat infections
- ketoconazole, itraconazole, posaconazole and voriconazole used to treat certain fungal infections

**Some medicines and VYTORIN may interfere with each other. These medicines may be affected by VYTORIN, may affect how well it works, or may increase the risk of side effects with VYTORIN. You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times. These include:**

- certain hepatitis C antiviral agents, such as elbasvir, or grazoprevir
- bile acid sequestrants, such as colestyramine, used to lower cholesterol levels.
- other medicines to lower cholesterol levels, for example, other fibrates, nicotinic acid (also known as niacin).
- warfarin, fluindione, ticagrelor or other drugs used to prevent blood clots
- colchicine, used for gout
- verapamil, used to treat high blood pressure and angina
- diltiazem, used to treat angina
- amiodarone, used to treat irregular heart beat
- amlodipine, used to treat high blood pressure and angina
- digoxin, used to treat heart failure

- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

**Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking VYTORIN.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYTORIN.**

## **4. How do I use VYTORIN?**

### **How much to take**

- The recommended dose in adults (18 years and over) is one VYTORIN 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening. Your doctor will adjust your VYTORIN dose depending on your response.
- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one VYTORIN 10/10, 10/20 or 10/40 tablet once a day, in the evening. The maximum recommended dose in adolescents is 10/40 mg.
- Because of the increased risk of muscle problems, the VYTORIN 10/80 tablet is only for patients at high risk of heart disease problems who have not yet reached their cholesterol goal on lower doses.
- Swallow VYTORIN with a glass of water.

- Follow the instructions provided and take VYTORIN until your doctor tells you to stop.

## **When to take VYTORIN**

- VYTORIN should be taken once a day, in the evening. The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people this is at night when asleep. Therefore, VYTORIN is more effective when taken in the evening.
- Take VYTORIN about the same time each day. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.
- Taking VYTORIN at the same time each day will have the best effect. It will also help you remember when to take your dose.
- Your doctor may ask you to take VYTORIN with other cholesterol lowering agents such as bile acid sequestrants. If you are taking a bile acid sequestrant, such as colestyramine, take your VYTORIN either at least two hours before or four hours after taking the bile acid sequestrant.

## **How long to take it**

- VYTORIN helps lower your cholesterol. It does not cure your condition.
- Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down.

- You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking VYTORIN, your cholesterol levels may rise again.

## **If you forget to take VYTORIN**

VYTORIN should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you have trouble remembering to take your tablet, ask your pharmacist for some hints.**

## **If you use too much VYTORIN**

If you think that you have used too much VYTORIN, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using VYTORIN?**

### **Things you should do**

**Call your doctor straight away and stop taking VYTORIN if you become pregnant while you are taking VYTORIN.**

Have your blood fats checked when your doctor says, to make sure VYTORIN is working. Even if you are taking medicines to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Remind any doctor, dentist or pharmacist you visit that you are using VYTORIN.

If you are about to have elective surgery, tell your doctor that you are taking VYTORIN. Your doctor may suggest stopping the tablets a few days before surgery.

### **Things you should not do**

- Do not give VYTORIN to anyone else, even if they have the same condition as you.

### **Things to be careful of**

- Grapefruit juice should be avoided while taking VYTORIN. Grapefruit juice contains one or more

components that alter the metabolism of some medicines, including VYTORIN.

## **Things that may help your condition**

High cholesterol can be treated in two main ways.

### **Lifestyle Changes**

This includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for advice before increasing physical activity.

### **Medicines**

Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how VYTORIN affects you.**

There have been side effects reported with VYTORIN that may affect your ability to drive or operate machinery. Individual responses to VYTORIN may vary.

## **Drinking alcohol**

**Avoid drinking large quantities of alcohol.**

Drinking large quantities of alcohol may increase your chance of VYTORIN causing liver problems.



## Looking after your medicine

- Keep VYTORIN in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. If you take this medicine after the expiry date has passed, it may not work.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Muscle/skeleton related:</b></p> <ul style="list-style-type: none"> <li>• Muscle aches</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Stomach irritation</li> <li>• Diarrhoea</li> </ul> <p><b>Heart and circulation-related:</b></p> <ul style="list-style-type: none"> <li>• Hypertension</li> <li>• Hot flush</li> </ul> <p><b>Metabolism and nutrition-related:</b></p> <ul style="list-style-type: none"> <li>• Decreased appetite</li> </ul> <p><b>Head and nervous system-related:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> </ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"> <li>• Cough</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These are the more common side effects of VYTORIN or of either ezetimibe or simvastatin.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>General conditions:</b></p> <ul style="list-style-type: none"> <li>• Feeling tired</li> <li>• Pain</li> </ul>	
<p><b>Mood-related:</b></p> <ul style="list-style-type: none"> <li>• Depression</li> <li>• Trouble sleeping</li> </ul> <p><b>Head and nervous system-related:</b></p> <ul style="list-style-type: none"> <li>• Tingling or numbness of the hands or feet</li> <li>• Poor memory</li> <li>• Confusion</li> </ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>• Blurred vision and impaired vision</li> </ul> <p><b>Reproductive system or breast-related:</b></p> <ul style="list-style-type: none"> <li>• Erectile dysfunction</li> <li>• Gynaecomastia (breast enlargement in men) (very rare)</li> </ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"> <li>• Breathing problems including persistent cough and/or shortness</li> </ul>	<p><b>Tell your doctor if you notice any of these.</b></p> <p>These are rare side effects of ezetimibe or simvastatin.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<p>of breath, that may also occur with fatigue, unexplained weight loss or fever</p> <p><b>Muscle/skeleton related:</b></p> <ul style="list-style-type: none"> <li>• Muscle rupture (very rare)</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• Rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions) (very rare)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● skin rash and hives</li> <li>● severe skin problems</li> <li>● dark coloured urine</li> <li>● light coloured bowel motions</li> <li>● joint pain</li> <li>● bleeding or bruising more easily than normal</li> <li>● steady abdominal pain with nausea and vomiting.</li> <li>● weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath (symptoms of myasthenia).</li> </ul> <p>Liver problems can also occur and may be serious. Your doctor may do blood tests to check your liver. Symptoms may include:</p> <ul style="list-style-type: none"> <li>● feel tired or weak</li> <li>● loss of appetite</li> <li>● upper belly pain</li> </ul>	<p><b>Tell your doctor immediately if you notice any of these side effects.</b></p> <p>These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dark urine</li> <li>● yellowing of the skin or the white of your eyes.</li> </ul> <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Symptoms may include:</p> <ul style="list-style-type: none"> <li>● unexplained muscle aches, tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping VYTORIN).</li> </ul> <p>The risk of muscle breakdown is greater at higher doses of VYTORIN, particularly the 10/80 mg dose and is greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

In adolescent patients (10 to 17 years of age) there have been no studies longer than 1 year of the effect of taking VYTORIN on bone development, growth, social and emotional development, or fertility.

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What VYTORIN contains**

<b>Active ingredients (main ingredients)</b>	ezetimibe 10 mg per tablet
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	simvastatin 10, 20, 40 or 80 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	butylated hydroxyanisole citric acid monohydrate croscarmellose sodium hypromellose lactose monohydrate magnesium stearate microcrystalline cellulose propyl gallate
<b>Potential allergens</b>	VYTORIN contains lactose.  VYTORIN does not contain gluten, sucrose, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What VYTORIN looks like**

VYTORIN comes in four different strengths:



VYTORIN 10/10 mg is a white to off-white, capsule shaped, biconvex compressed tablet marked with "311". (AUST R 98100)

VYTORIN 10/20 mg is a white to off-white, capsule shaped, biconvex compressed tablet marked with "312". (AUST R 98111)

VYTORIN 10/40 mg is a white to off-white, capsule shaped, biconvex compressed tablet marked with "313". (AUST R 98115)

VYTORIN 10/80 mg is a white to off-white, capsule shaped, biconvex compressed tablet marked with "315". (AUST R 98117)

## **Who distributes VYTORIN**

Organon Pharma Pty Limited

Building A, 26 Talavera Road

MACQUARIE PARK NSW 2113

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